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Lyle Jaffe
FDA Dockets Management Branch

Via **Facsimile**: 301-827-6870

Re: **Docket No. 99P-4613 (PLEASE INCLUDE IN OFFICIAL DOCKET)**

Dear Mr. Jaffe:

A number of assumptions made regarding protein absorption and digestion were incorrectly applied to Monsanto's **rbGH** approval process. The major flaw in **CVM's** evaluations regarding human safety was based upon the assumption that neither **rbGH** nor IGF-I poses any biological activity when administered orally.

The internal review from Health Canada reveals just the opposite. In reviewing the "**90-Day Study**", (that study actually lasted for 180 days) FDA found no evidence of following **oral** administration of **rbGH**. The Canadian government found something quite different, The internal **rbGH** review executive **summary** revealed:

"The **90-day subchronic** rat study submitted by **Monsanto** showed that **rbST (rbGH)** can be absorbed intact in G.I. tract following oral administration of high doses and elicit a **primary antigenic response (IgG antibodies)**. The **full immunological, and potential toxicological consequences of this observation were not assessed by HSD**. Prior to drawing any definitive conclusions regarding the **safety of rbST and IGF-I residues**, it is recommended that HSD examines the findings of the study, including **pertinent histopathologic data, to confirm the sponsors (Monsanto) contention** that they are not relevant to humans"

It is clear the Canadian Scientists found something that FDA scientists missed. The reason FDA scientists missed **this** was made clear to me at my April 21, 1995 meeting with FDA – the key study was never reviewed.

An interesting event occurred on May 11, 1994, it was Health Canada's review for Monsanto's **rbGH**. Reports contained in locked file cabinets were stolen from Dr. Hayden's office. After she **realized** they were missing and filed a complaint, files were "re-stuffed in a sloppy manner" on Monday, May 16, 1994, without her knowledge **or** approval. A subsequent investigation by the Royal Canadian Mounted Police found no fingerprints and did not **identify** who accessed the file and what documents (if any) were missing. It is my belief that the second **90-day** portion of the Richard study was surreptitiously removed from that file. CVM has that document and its **review** should be made as **part of** the review for this petition (Docket No. 99P-4613).

Sincerely,



Robert Cohen

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